10/566054

Attorney's Docket No.: 06275-492US1 / 101170-1P US

ÇTITO 25 JAN 2006 IN THE UNITED STATES PATENT

Applicant: Helen Ambrose et al.

Art Unit : Unknown

Serial No.: To Be Assigned

Examiner: Unknown

Filed

: Herewith

Title

: USE OF POLYMORPHISMS IN HUMAN OATP-C ASSOCIATED WITH AN

EFFECT ON STATIN PHARMACOKINETICS IN HUMANS IN STATIN

THERAPY

MAIL STOP PCT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request. A copy of a communication from a foreign patent office in a counterpart application is also enclosed.

This statement is being filed with the application. Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 06275-492US1.

Respectfully submitted,

Manis K. Fraser, Ph.D., J.D. Reg. No. 34,819

Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110

Telephone: (617) 542-5070 Facsimile: (617) 542-8906

21253695.doc

CERTIFICATE OF MAILING BY EXPRESS MAIL

Express Mail Label No. EV 664075161 US

January

Date of Deposit

Sheet <u>1</u> of <u>2</u>

Substitute Form PTO-1449 (Modified)

U.S. Department of Commerce Patent and Trademark Office

Attorney's Docket No. 06275-492US1

Information Disclosure Statement by Applicant (Use several sheets if necessary)

Applicant Helen Ambrose et al.

Filing Date Herewith

Group Art Unit

(37 CFR §1.98(b))

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2002/090622	07/11/2002	Jetson et al.	1		, in the second
	AB	2004/0235006	11/25/2004	Adeokun et al.			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner	Desig.	Document	Publication	Country or	.,		Trans	lation
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No

Other Documents (include Author, Title, Date, and Place of Publication)				
Examiner	Desig.			
Initial	ID	Document		
AC		Akey et al., "Haplotypes vs single marker linkage disequilibrium tests: what do we gain?",		
	I III	European Journal of Human Genetics 9:291-300 (2001)		
	AD	Anonymous: "OATP-C: SLC01B1" Genecards, October 18, 2005; Retrieved from the Internet:		
		URL:http://www.genecards.org/cgi-bin/carddisp?SLC01B1&search=oatp-c&suff=txt		
		Anonymous: "GeneCard for protein-coding SLCO1B1" Genecards, 'Online! XP002317182		
	AE	Retrieved from the Internet: <u>URL:http://genecards.weizmann.ac.il/cgi-</u>		
	ļ	bin/cards/carddisp?SLC01B1&search=oatp-c&suff=txt (Document not attached)		
		Anonymous: "SNP linked to Gene (geneID: 10599)" Single Nucleotide Polymorphism, 'Online!		
	AF	XP002320267 retrieved from the internet:		
		URL:http://www.ncbi.nlm.nih.gov/SNP//snp_ref.cgi?locusId=10599>		
	AG	Calafell et al., "Haplotype Evolution and Linkage Disequilibrium: A Simulation Study", Hum Hered		
		51:85-96 (2001)		
		Database EMBL 'Online! 15 March 2000, "Homò sapiens chromosome 11 clone RP11-484D2,		
	AH	Working Draft Sequence, 22 unordered pieces." XP002317183 retrieved from EBI accession no.		
		EM_PRO:AC025552 Database accession no. AC025552		
	AI	Igel et al., "Pharmacology of 3-Hydroxy-3-Methylglutaryl-Coenzyme A Reductase Inhibitors		
		(Statins), Including Rosuvastatin and Pitavastatin", J Clin Pharmacology 42:835-845 (2002)		
	AJ	Jorde, "Linkage Disequilibrium and the Search for Complex Disease Genes", Genome Research		
		10:1435-1444 (2000)		
	AK	Jung et al., "Characterization of the Human OATP-C (SLC21A6) Gene Promoter and Regulation of		
		Liver-specific OATP Genes by Hepatocyte Nuclear Factor 1a", J. Biol. Chem. 276(40):37206-		
	ļ	37214 (2001)		
		Kim, "3-Hydroxy-3-methylglutaryl-coenzyme A reductase inhibitors (statins) and genetic variability		
	AL	(single nucleotide polymorphisms) in a hepatic drug uptake transporter: What's it all about?",		
	 	Clinical Pharmacology & Therapeutics 75(5):381-385 (2004)		
	AM	König et al., "A novel human organic anion transporting polypeptide localized to the basolateral		
		hepatocyte membrane", Am. J. Physiol. Gastrointest. Liver Physiol. 278:G156-G164 (2000)		
	AN	Kruglyak, "Prospects for whole-genome linkage disequilibrium mapping of common disease genes",		
		Nature Genetics 22:139-144 (1999)		
	AO	Mwinyi et al., "Evidence for inverse effects of OATP-C (SLC21A6) *5 and *1b haplotypes on		
	L	pravastatin kinetics", Clinical Pharmacology & Therapeutics 75(5):415-421 (2004)		

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if no	ot in conformance and not considered. Include copy of this form with

next communication to applicant.

IAP20 Resulting 25 John 2006 2

Substitute Form PTO-1449 (Modified)

U.S. Department of Commerce Patent and Trademark Office Attorney's Docket No. 06275-492US1

Application No. 6054

Information Disclosure Statement by Applicant

(Use several sheets if necessary)

Applicant
Helen Ambrose et al.

Filing Date Herewith

Group Art Unit

(37 CFR §1.98(b))

Examiner	Desig.	ocuments (include Author, Title, Date, and Place of Publication)
Initial	ID	Document t
	AP	Niemi et al., "High plasma pravastatin concentrations are associated with single nucleotide polymorphisms and haplotypes of organic anion transporting polypeptide-C (OATP-C, SLCO1B1)", Pharmacogenetics 14:429-440 (2004)
	AQ	Nishizato et al., "Polymorphisms of OATP-C (SLC21A6) and OAT3 (SLC22A8) genes: Consequences for pravastatin pharmacokinetics", Clinical Pharmacology & Therapeutics 73(6):554-565 (2003)
	AR	Nozawa et al., "Genetic Polymorphisms of Human Organic Anion Transporters OATP-C (SLC21A6) and OATP-B (SLC21A9): Allele Frequencies in the Japanese Population and Functiona Analysis", J. Pharmacology and Experimental Therapeutics 302(2):804-813 (2002)
	AS	Reich et al., "Linkage disequilibrium in the human genome", Nature 411:199-204 (2001)
	AT	Stephens et al., "Haplotype Variation and Linkage Disequilibrium in 313 Human Genes", Science 293:489-493 (2001)
	AU	Tamai et al., Molecular Identification and Characterization of Novel Members of the Human Organic Anion Transporter (OATP) Family", Biochemical and Biophysical Research Communications 273:251-260 (2000)
	AV	Tirona et al., "Pharmacogenomics of organic anion-transporting polypeptides (OATP)", Advanced Drug Delivery Reviews 54:1343-1352 (2002)
	AW	Tirona et al., "Polymorphisms in OATP-C. Identification of multiple allelic variants associated with altered transport activity among European- and African-Americans", J. Biol. Chem. 276(38):35669-35675 (2001)
	AX	Toivonen et al., "Data Mining Applied to Linkage Disequilibrium Mapping", Am. J. Hum. Genet. 67:133-145 (2000)
	AY	Weiss et al., "Linkage disequilibrium and the mapping of complex human traits", TRENDS in Genetics 18:19-24 (2002)
AZ		Zhang and Zhao, "Linkage Disequilibrium Mapping with Genotype Data", Genetic Epidemiology 22:66-77 (2002)

Examiner Signature	Date Considered	-;	
	74*	ŧ	
EVANINED, toldiele citeties and desired Desired			

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.